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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,328	11/18/2003	Richard A. Terwilliger	WORLD-01004US2	5231

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EXAMINER	
VENIAMINOV, NIKITA R	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/716,328	TERWILLIGER ET AL.	
	Examiner	Art Unit	
	Nikita R Veniaminov	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-6 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-6 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 04/05/2004.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 04/05/2004 is being considered by the examiner.

Specification

2. The disclosure is objected to because of the following informalities: The Priority information on page 1, section **[0001]**, line 2 should be changed as follows: the phrase "now a Patent No. 6,786,858 B2" should be inserted after the phrase "2002,". Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-3 are rejected under 35 U.S.C. 102(e) as anticipated by Kaplan (US 6,514,193) or, in the alternative, under 35 U.S.C. 103(a) as obvious over

Kaplan (US 6,514,193) in view of Mentor Corporation (NASD, MNTR) cited by Applicant.

Kaplan ('193) teaches a prescription method of treating tissue comprising the steps of:

(Claim 1) first accepting a tissue treatment plan for the tissue to be treated, which treatment plan specifies a number and spacing of treatment seeds to be provided in a strand (see column 14, lines 25-41; column 15, lines 57-67 and column 16, lines 1-20. Examiner states, that a prescription method of treating tissue comprising the step of accepting a tissue treatment plan is inherently exists in the invention of Kaplan ('193). The seed chains are made using different sized spacers to deliver a "predetermined" amount of radiation. It would not be possible to pre-make these seed chains unless a plan has been selected); second creating a treatment strand by threading treatment seeds onto a material (see Figure 5A and 5B; column 14, lines 25-41 and column 15, lines 1-20); and third fixing the seeds at intervals on the material, wherein at least some of the intervals can be independently set to a desired length (see Figures 5A - 5B and column 14, lines 34-41);

(Claim 2) wherein said tread fixing step is performed be crimping the material (see column 15, lines 1-3);

(Claim 3) wherein said first accepting step accepts a treatment plan that specifies radioactive seeds and optimal spacings between each pair of seeds (see column 14, lines 25-41; column 15, lines 57-67; column 16, lines 1-20 and

Examiner's explanation above); and wherein said second creating step creates strands to the specified optimal spacings prescribed (see column 14, lines 25-41; column 15, lines 57-67; column 16, lines 1-20).

Kaplan ('193) implicitly teaches the steps of a prescription method of treating tissue, as described above, but he does not explicitly teach a step of accepting tissue treatment plan of the tissue to be treated. However, Mentor Corporation (NASD, MNTR) teaches a step of accepting a tissue treatment plan for the tissue to be treated, which plan specifies a number and spacing of treatment seeds to be provided in a strand. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the method steps of Mentor Corporation (NASD, MNTR) with the treatment plan of Kaplan ('193) to provide greater planning flexibility, improved safety, improved control and better documentation.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan (US 6,514,193) as applied to claim 1 above, in view of Rapach et al. (US 2004/0015037 A1). Kaplan ('193) teaches the steps of a prescription method of

treating tissue, as described in paragraph 5 above, but he does not teach a method, wherein a second creating step is performed positioning radioactive seed in a mold at the optimal spaces and pouring in a material to mold the radioactive seeds in place. However, Rapach et al. ('5037) teach a method step comprising introducing a plurality of radioactive seeds into a mold and pouring in a material to mod the radioactive seeds in place (see page 2 [0016] – [0021]. In the absence of showing any criticality, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the method step of Rapach et al. ('5037) in the method steps of Kaplan ('193) to provide a plurality of radioactive seeds securely retained and spaced in the braided, flexible material, and a different method to make the same product.

8. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan (US 6,514,193) in view of Rapach et al. (US 2004/0015037 A1) as applied to claims 1 and 4 above, and further in view of Reit et al. ("ULTRASONICALLY GUIDED TRANSPERINEAL SEED IMPLANTATION OF THE PROSTATE: MODIFICATION OF THE TECHNIQUE AND QUALITATIVE ASSESSMENT OF IMPLANTS") cited by Applicant. Kaplan ('193) and Rapach et al. ('5037) teach a prescription method of treating tissue as described in paragraph 7 above, but they do not teach a method, wherein a first accepting step accepts a treatment plan created an imaging device. However, Reit et al. teach an ultrasonically guided (guided by an imaging device) imp0lantation

techniques, which allows for planning of the optimal seed configuration (see page 555, left column, lines 19-24; page 555, right column, lines 5-17 and page 556, right column, lines 41-47). In the absence of showing any criticality, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the method step of Reit et al. with the method steps of Kaplan ('193) and Rapach et al. ('5037) to accept a plan for an ideal seeds distribution and optimal seeds configuration.

9. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan (US 6,514,193) as applied to claim 1 above, in view of Mentor Corporation (NASD, MNTR) cited by Applicant. Kaplan ('193) teaches the steps of a prescription method of treating tissue, as described in paragraph 5 above, but he does not teach a method, wherein a first accepting step accepts a treatment plan created using a software program to specify intervals between seed position. Mentor Corporation (NASD, MNTR) teaches a method of using a standard 3-D treatment planning software to specify intervals between seed positions (see page one, lines 11-27). In the absence of showing any criticality, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the software of Mentor Corporation (NASD, MNTR) in the treatment plan of Kaplan ('193) to provide greater planning flexibility, improved safety, improved control and better documentation.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Terwilliger et al. ('858).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikita R Veniaminov whose telephone number is (703) 605-0210. The examiner can normally be reached on Monday-Friday 8 A.M.-5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nikita R Veniaminov
Examiner
Art Unit 3736

September 27, 2004.

SAMUEL G. GILBERT
PRIMARY EXAMINER